

A randomised controlled trial of thyroxine in preterm infants under 28 weeks gestation

Submission date 20/03/2007	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 10/03/2008	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 15/07/2013	Condition category Neonatal Diseases	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2005-003099-39

Protocol serial number
MRC ref: G0501788; LWH0604

Study information

Scientific Title

Acronym

TIPIT (Thyroxine In Preterm Infants Trial)

Study objectives

Thyroxine supplementation given to extreme preterm infants postnatally until 32 weeks postmenstrual age modulates brain development and size, the Hypothalamic-Pituitary-Adrenal axis (HPT) and somatic growth.

More details can be found at: <http://www.mrc.ac.uk/ResearchPortfolio/Grant/Record.htm?GrantRef=G0501788&CaseId=6765>

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the North West Multicentre Research Ethics Committee (ref: 07/MRE08/37)

Primary study design

Interventional

Study design

Randomised double-blinded placebo controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Premature infants

Interventions

In the initial phase, infants will receive either intravenous thyroxine or placebo at 8 mcg/kg birth weight/day single daily dose. In the next phase, once enteral feeds are fully established, oral thyroxine or placebo will be given at 8 mcg/kg birth weight/day single daily dose until the baby reaches 32 weeks CGA.

Details of Joint Sponsor:

University of Liverpool

Liverpool

L69 3BX

United Kingdom

Tel: +44 (0)151 794 2000

<http://www.liv.ac.uk/>

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Thyroxine

Primary outcome(s)

The primary outcome will be the width of the sub-arachnoid space measured using cranial ultrasound and head circumference at 36 weeks Corrected Gestational Age (CGA).

Key secondary outcome(s)

1. Width of the sub-arachnoid space measured using cranial ultrasound at 36 weeks Corrected Gestational Age (CGA)
2. Head circumference at 36 weeks CGA

Completion date

01/12/2009

Eligibility

Key inclusion criteria

All infants with gestational age under 28 weeks at birth

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

Key exclusion criteria

1. Infants born to mother with known thyroid disease or on antithyroid medications during pregnancy
2. Infants born to mother who are on amiodarone during pregnancy
3. Infants diagnosed with major congenital or chromosomal abnormalities known to affect thyroid function or brain development
4. Maternal death during or within 5 days after childbirth

Date of first enrolment

01/06/2007

Date of final enrolment

01/12/2009

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

School of Reproductive and Developmental Medicine

Liverpool

United Kingdom

L8 7SS

Sponsor information

Organisation

Liverpool Women's NHS Foundation Trust (UK)

ROR

<https://ror.org/04q5r0746>

Funder(s)

Funder type

Government

Funder Name

Medical Research Council (UK)

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Funder Name

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	11/07/2013		Yes	No
Protocol article	protocol	26/03/2008		Yes	No
Protocol article	MRI protocol	30/06/2008		Yes	No